Date: February 24, 2010
To: Jon Perlin, Chair
             John Halamka, Co-Chair
             Health Information Technology Standards Committee
From: Dixie Baker, Chair
             Steve Findlay, Co-Chair
             Privacy and Security Workgroup
Subject: Additional Comments from Privacy and Security Workgroup Members

In the course of conducting our review of the Interim Final Rule (IFR), some members of the Privacy and Security Workgroup expressed concerns about topics other than privacy and security, and applicable to more than just the IFR. We offer these comments for your consideration, and with the request that you forward these comments to the appropriate parties. Thank you.

1. Topic: Administrative Transactions
    Document References: p 2032; Table 2A (p 2033); p 2043, §170.205(d)

    Comment: While not a specific topic for privacy and security, we have concerns about the expectation that Certified EHR Technology will include the capability to generate administrative transactions (claims, eligibility) since this is not a capability that EHR technology provides.

    We are concerned about the inclusion of administrative transactions, claims submission and eligibility, as part of Certified EHR Technology, and the associated Meaningful Use measure of 80% electronic submission of claims and eligibility. Our concern is threefold. First, HIPAA explicitly enables an entity to use a clearinghouse to perform these transactions and need not perform them directly from its practice management systems or EHR, and organizations commonly use clearinghouses for this purpose. Many providers lack the capability to create and submit fully HIPAA-compliant transactions from their internal systems.

    Second, most "Complete EHR" systems that exist today to not have the capability to perform HIPAA administrative transactions, and most stand-alone administrative systems do not have claims submission and eligibility modules that could be easily isolated and converted into "EHR Modules." Integrating these administrative capabilities into EHR systems would require not only technical changes, but also operational and workflow changes, which would be quite expensive for both vendors and eligible professionals and hospitals. Adapting workflow to accommodate new EHR technology offers real benefits in quality and patient safety, as well as operational efficiency. Replacing administrative systems and changing administrative workflows that are working well today seems to serve no real purpose.

    Third, if claims and eligibility transactions are performed using EHR technology, they will render the transaction a "disclosure" accountable under the new accounting of disclosures provision of the Health Information Technology for Economic and Clinical Health (HITECH) Act – as a 'payment' disclosure done 'through an EHR' (as is stated in HITECH).

    Recommendation: We recommend that electronic claims submission and eligibility be removed as a meaningful-use measure and as a certification criterion for EHR technology.

2. Topic: Newborn Screening (NBS)

Document Reference: p 2029, column 3

Comment: Newborn screening results are the first meaningful health information exchange in any American's life. The proposed vocabulary requirements leave out a major sector of the health system that would greatly benefit from data standardization and, in turn, benefit the health system overall. Stage 1 of meaningful use certification should me amended to include standard vocabularies that directly address newborn screening and its interoperability with electronic health records.

The newborn screening system is a federally mandated public health program and it experiences considerable disparities between the standards of collection, storage, and transmission of information by each state. In 2006 over 4 million babies were screened by state newborn screening labs[1] and despite the large portion of the population that is served annually, standards have yet to be harmonized between these state systems. To remedy this discontinuity, Genetic Alliance suggests that the Office of the National Coordinator consider the implementation of the Newborn Screening Coding and Terminology Guide[2], developed by the National Library of Medicine, as the vocabulary standard for the inclusion of newborn screening data into electronic health records.   By including newborn screening specific language in stage 1 of meaningful use certification, electronic health record systems will be able to meaningfully capture and collect data about negative and out of range newborn screenings in a way that will facilitate the information being used for clinical decision support and secondary research purposes in future stages.

If no standard for newborn screening information is included in the first stage of meaningful use certification there will be terms for which no LOINC, ICD9, or SNOMED CT coding exist. This will create chaos in the very first health information exchange that every American experiences. It will not be possible to include the NBS result in the electronic medical records of newborns. Information entered as free text poses a risk that those fields may be left out of a record if the transmitting or receiving electronic medical record system does not have a reciprocal field. Furthermore, information kept as free text will not be as easily indexed by electronic medical systems and for this reason it will be less likely that the whole records will meaningfully used by provider and payer systems. The NBS system, since it exists in all 50 states and territories, should be an excellent model system for electronic health information exchange in the service arena. This is a unique opportunity for both public and personal health – the first health information exchange in a mandated services system that needs integration across several entities.

Recommendation: Include NBS as a Stage 1 meaningful use measure. Include NBS certification criteria and vocabulary standards in the certification of EHR systems to enable them to capture and collect enough data to be meaningfully used for clinical decision support in later stages of certification.

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[1] National Newborn Screening Information System (NNSIS) http://www2.uthscsa.edu/nnsis/

[2] Newborn Screening Coding and Terminology Guide. National Library of Medicine. http://newbornscreeningcodes.nlm.nih.gov/